K010686

MAR 21 2001

SECTION 2: 510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is K010686.

DATE OF SUBMISSION: FEBRUARY 26, 2001

SUBMITTER:
Mr. Frederick Tse
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ESTABLISHMENT REGISTRATION NO: #9615449

OFFICIAL CONTACT:
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GLOBALSHOP INC.
PO BOX 1211
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TELEPHONE: 201-444-7204
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TRADE NAME: KTJ-20C™ BLOOD PRESSURE CUFF

COMMON/USUAL NAME: BLOOD PRESSURE CUFF

CLASSIFICATION NAME: CUFF, BLOOD PRESSURE (CFR 870.1120)

CLASSIFICATION PANEL: CARDIOVASCULAR

PREDICATE DEVICE: ADCUFF™
AMERICAN DIAGNOSTIC CORP. (K962655)

INTENDED USE
The KTJ-20C™ blood pressure cuff is used in conjunction with non-invasive blood pressure measurement systems by personnel properly trained. The device is non-sterile and is intended as a reusable multi-patient device for measuring one's blood pressure. It is available in child through large adult sizes.

5K3

DEVICE DESCRIPTION

The device is comprised of one or two tubes attached to an inflatable latex bladder, which is covered with a stitched nylon or cotton cover. The device is wrapped around a patient's limb and secured by a hook and loop closure. The tubing connects to a non-invasive blood pressure measurement system. Sizes will include child through large adult. Each cuff will be packaged in a polyethylene bag.

COMPARISON WITH PREDICATE DEVICE

ITEM	KTJ-20C™ BLOOD PRESSURE CUFF	ADCUFF™ (K962655)
INTENDED USE	INDIRECT MEASUREMENT OF BLOOD PRESSURE	INDIRECT MEASUREMENT OF BLOOD PRESSURE
ANATOMICAL SITES OF USE	UPPER ARM	UPPER ARM
INTENDED POPULATION	CHILD – LARGE ADULT	NEWBORN – LARGE ADULT
LABELING	SEE SECTION 5A	SEE SECTION 9A
OUTER MATERIAL	NYLON FABRIC OR COTTON	NYLON FABRIC OR COTTON
BLADDER MATERIAL	LATEX	LATEX
CUFF CLOSURE	VELCRO	VELCRO
PRESSURE LIMITS	0 – 300 mmHg	0 – 300 mmHg
USABLE LIFE	10,000 INFLATION	10,000 INFLATION
NUMBER OF TUBES	1 and 2	1 and 2

PERFORMANCE DATA

The KTJ-20C™ blood pressure cuff was compared to the **ADCUFF™** blood pressure cuff to confirm its functional and physical performance characteristics were equivalent. The AAMI SP9: 1994 standard was used to select the relevant performance attributes to measure. The cuffs were equivalent in performance in regards to Cuff Closure, Pressure Capacity and Repeated Inflations as required under the SP9 standard.

CONCLUTION

In accordance with the FDA 21CFR807 and based on the information provided in this premarket notification, Golden Horse Medical Equipment Co. Ltd. concludes that the KTJ-20C™ is safe, effective and substantially equivalent to the ADCUFF predicate device as described herein and meets the relevant requirements of ANSI/AAMI SP9-1994.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2001

Golden Horse Medical Equipment (Wuxi) Co., Ltd.
c/o Mr. Ned E. Devine, Jr.
Entela, Inc.
3033 Madison Avenue, SE
Grand Rapids, MI 49548

Re: K010686
Trade Name: KTJ-20C™ Blood Pressure Cuff
Regulatory Class: II (two)
Product Code: 74 DXQ
Dated: March 2, 2001
Received: March 8, 2001

Dear Mr. Devine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 5B: INDICATIONS FOR USE

510(k) Number (if known): K010686

Device Name: KTJ-20C™ BLOOD PRESSURE CUFF

INDICATIONS FOR USE

Personnel properly trained in the use of blood pressure measurement devices use the KTJ-20C™ blood pressure cuff in conjunction with non-invasive blood pressure measurement systems. The device is non-sterile and is intended as a reusable multi-patient device. It is available in child through large adult sizes.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010686

(Optional Format 3-10-98)